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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,590	09/29/2003	Martin Bill	7500.410US01	4484

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

DEJONG, ERIC S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,590

Applicant(s)

BILL, MARTIN

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/22/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED OFFICE ACTION

Election/Restrictions

Applicant's election of Species A (claims 2-9) in the reply filed on 03/15/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further review, the species election requirement set forth in the Office action mailed 02/16/2006 is withdrawn and all claims have been rejoined for examination on the merits.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Methods of Comparing a First Data Set With A Second Data Set.

The disclosure is objected under 37 CFR § 1.77 for not providing a heading for each section of the specification as outline by the following guidelines. These guidelines are suggested for the applicant's use.

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

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upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-7 and 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-7 each recite the limitation of "the reading" (see line 1 of claim 3, line 1 of claim 4, line 1 of claim 5, line 1 of claim 6, and line 1 of claim 7). There is insufficient antecedent basis for this limitation in the instant claims as claim 2, from which claim 3-7 depend) recites two separate readings for a first and second DNA sample. As such, it is unclear which of the two previously recited readings the limitation of "the reading" is intended to refer.

For the purpose of continuing examination, the limitation of "the reading" in claims 3-7 has been construed to read on either or both the two reading as recited in instant claim 2.

Regarding claim 4, the phrase "ideally" (see line 3 of the instant claim) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 5, the phrase "ideally" (see line 3 of the instant claim) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Regarding claim 9, the phrase "for instance" in lines 6 and 7 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim 9 further recites the limitation of

"Pr(Data/HPData & Other information)

Pr(Data/HpData & Other information)"

In lines 3 and 4 of the instant claim. The instant claim further defines this limitation as an expression of the probability of one raw data situation considered against the probability of the raw data given another raw data situation. As written, there is no distinction between the two probability terms in the numerator and the denominator of the expression and as such the resultant ratio of the two Pr terms can only be unity (1). Further, if the expression is construed to read as the ratio of distinct probabilities, the metes and bounds of the instant claim are rendered indefinite as neither the instant claim nor the specification provide a definition for the information that is included in "Data/HPData & Other information".

Claim 9 further recites the limitations of "the probability of the raw data" and "raw data" in lines 5-7 of the instant claim. There is insufficient antecedent basis for this limitation in the instant claims as claim 2, from which claim 9 depends, does not recite either of the terms "probability" or "raw data".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al.

The instant claims are drawn to methods of comparing a first data set with a second data set comprising obtaining from said data sets from a first and second sample, respectively, by subjecting said samples to a technique which provides a detectable indication of different characteristics of different components of said samples, and taking a readings of the detectable indication thereby forming said first and second data sets, and comparing the readings of the detectable indication for the first and second sample.

[Claims 1, 2, and 10]: Klein et al. set forth methods for comparing different protocols for DNA extraction from hemolyzed and nonhemolyzed human and mouse sera in order to test their efficacy in obtaining DNA suitable for PCR amplification analysis (see Klein et al., Abstract and page 1897, col. 1, lines 16-23). HBV DNA was isolated from spiked samples of human (a first sample) and mouse (a second sample) sera, wherein said samples were subjected to purification using the QIAamp kit followed by PCR amplification (see Klein et al., captions of Figures 1 and 2, page 1897, col. 2, lines 13 through page 1898, col. 1, line 26). Klein et al. demonstrate a comparison of

HBV DNA detection in human and mouse sera resulting from varying extraction protocols by gel electrophoresis (see Klein et al., Figures 1 and 2 and page 1898, col. 1, line 27 through page 1899, col. 1, line 21).

[Claim 3]: The readings obtained by Klein et al. on HBV DNA from human and mouse sera were not processed in any way following gel electrophoresis.

[Claim 4]: The readings obtained by Klein et al. on HBV DNA from human and mouse sera from gel electrophoresis did not involve any consideration of allele position, size, length identity or quantity.

[Claim 5]: The readings obtained by Klein et al. on HBV DNA from human and mouse sera from gel electrophoresis did not involve any consideration of SNP position, size, identity, quantity, or intensity.

[Claim 6]: The readings obtained on Klein et al. HBV DNA from human and mouse sera from gel electrophoresis did not exclude any data relating to the detection of HBV DNA.

[Claim 7]: The readings obtained on Klein et al. HBV DNA from human and mouse sera from gel electrophoresis are unprocessed raw data that did not involve any interpretation of HBV DNA levels.

[Claim 8]: The readings obtained on Klein et al. HBV DNA from human and mouse sera from gel electrophoresis were first prepared and stored in a gel electrophoretic medium prior to analysis, which reads on the instantly claimed limitation at least one of the readings being stored in a database prior to comparison.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

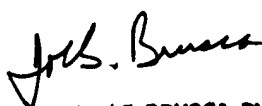
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EDJ



 24 May 2006
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER